**CUSTOMER NO.: 38107**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

| | | |
|---|---|---|
| In re application of:<br>J. RUSSELL, et al. | ) | Examiner: N. LAVERT |
| | ) | Art Unit: 4123 |
| Serial No.: 10/597,079 | ) | |
| | ) | Confirmation: 6955 |
| Filed: July 11, 2006 | ) | |
| | ) | |
| For: **ADAPTIVE PHYSIOLOGICAL MONITORING SYSTEM AND METHODS OF USING SAME** | ) | |
| | ) | |
| Date of Final Office Action:<br>August 22, 2008 | ) | |
| | ) | |
| Attorney Docket No.:<br>PHUS040020US2/PKRZ201268 | ) | Cleveland, OH 44114<br>February 11, 2009 |

# BRIEF ON APPEAL

---

CERTIFICATE OF ELECTRONIC TRANSMISSION

I certify that this **BRIEF ON APPEAL** and accompanying documents in connection with U.S. Serial No. 10/597,079 is being filed on the date indicated below by electronic transmission with the United States Patent and Trademark Office via the electronic filing system (EFS-Web).

February 13, 2009
Date

Patricia A Heim
Patricia A. Heim

## I. STATEMENT OF REAL PARTY IN INTEREST (41.37(f))

The real party in interest for this appeal and the present application is Koninklijke Philips Electronics N.V.

## II. STATEMENT OF RELATED CASES (41.37(g))

None

## III. JURISDICTIONAL STATEMENT (41.37(h))

The Board has jurisdiction under 35 U.S.C. 134(a).

The Examiner mailed a final rejection on August 22, 2008, setting a three-month shortened statutory period for response.

The time for responding to the final rejection expired on November 22, 2008. Rule 134.

A notice of appeal and request for one-month extension of time were filed on December 18, 2008.

The time for filing an appeal brief is two months after the filing of a notice of appeal. Bd.R. 41.37(c). The time for filing an appeal brief expires on February 18, 2009.

The appeal brief is being filed on the date set forth on the Certificate of Transmission.

## IV. TABLE OF CONTENTS (41.37(i))

Page

## V. TABLE OF AUTHORITIES (41.37(j))

Not Applicable

## VI. STATUS OF AMENDMENTS (41.37(l))

Amendment C of October 16, 2008 was entered.

The 37 CFR 1.1144 Petition (Restriction Requirement) of October 16, 2008 has not yet been decided.

## VII. GROUNDS OF REJECTION TO BE REVIEWED (41.37(m))

Whether claims 9-12, 15, 17, 25, 27-30, and 34 are anticipated in the sense of 35 U.S.C. § 102 by Nolan (US 5,404,877).

Whether claims 13 and 15 are patentable in the sense of 35 U.S.C. § 103 over Nolan as modified by Toda (US 2002/0036446).

Whether claims 23 and 31-33 distinguish patentably over the references of record, if the 37 CFR 1.144 Petition is granted.

## VIII. STATEMENT OF FACTS (41.37(n))

1. Claim 9 calls for one or more electrocardiography electrodes (claim 9, lines 17-18).

2. Rather than using electrodes (Nolan, column 2, lines 44-50), Nolan uses a coil 6 which generates an electromagnetic field which is altered by movement of nearby tissue (Nolan, column 9, lines 63 – column 11, line 19).

3. Nolan discloses an antenna system 12 including an antenna coil 6 (Nolan, column 9, line 63 – column 10, line 5).

4. The coil 6 generates an electromagnetic field which impinges on organs that move or change in size, which motion or dimensional variability causes the input impedance of the coil 6 to change (Nolan, column 10, lines 47-56).

5. An impedance measurement circuit 14 measures the impedance of current flow between the antenna and the body (Nolan, column 9, line 63 – column 10, line 17).

6. More specifically, the impedance measurement circuit applies a voltage to the coil 6 (Nolan, column 11, line 62 – column 12, line 11).

7. When the impedance measurement circuit generates measuring currents at the appropriate frequencies, the impedance which it

measures reflects movements relating to respiration and to cardiac motion (Nolan, column 12, line 51 – column 13, line 4).

8. The respiration and cardiac signals can be separated by frequency filtering (Nolan, column 7, line 51 – column 13, line 4; column 15, lines 35-54).

9. Claim 9 calls for determining whether activity sensor signals are above or below a predetermined threshold (claim 9, lines 25 28).

10. Nolan uses the activity signal to adjust the heart rate threshold with exercise (Nolan, column 20, lines 14-24; column 22, lines 24-67).

11. Claim 9 calls for adaptively controlling the communication of information (claim 9, lines 31-37).

12. When the cardiac level threshold of Nolan is exceeded or other alarm events occur, this information is communicated (Nolan, column 23, lines 44-68; column 24, lines 31-52).

13. On page 2 of the Advisory Action of November 5, 2008, the Examiner indicated that the claimed means for adaptively controlling the communication of information would require further search and/or further consideration (Advisory Action of November 5, 2008, page 2).

14. Claim 9 calls for adaptively controlling the communication of biological signal information to the patient through a user interface based on (1) the level of detected activity level to the

predetermined threshold of the access detector, (2) the electrocardiography signals relative to the preset threshold of the arrhythmia detector, and/or (3) the detected system errors relative to the predetermined criteria of the system error detector (claim 9, lines 31-37).

15. Although Nolan has different alarm communication modes, Nolan does not determine which one of these modes to use based on the sensor signals meeting predetermined thresholds (Nolan, column 9, lines 10-22).

16. Although Toda discloses that piezoelectric materials are known, the piezoelectric device of Toda is effective for the excitation of acoustic energy by a resonance effect (Toda, [0001]).

17. Nolan only determines whether an alarm condition has or has not been met (Nolan, column 9, lines 40-54).

18. Nolan communicates whenever the alarm condition is met (Nolan, column 25, lines 7-63).

19. Although Nolan can have different types of alarms, the selection of the type of alarm is determined by and under the direction of the downloaded program code (Nolan, column 9, lines 10-22).

20. Nolan issues the alarm signal based on an arrhythmia event, not on system malfunctions nor with the type of alarm being based on

whether the malfunction is classified as critical or non-critical (Nolan, column 25, lines 47-63).

21. Nolan adjusts the cardiac rate threshold in accordance with exercise and whether the patient's heart rate is normal or abnormal for the exercise or non-exercise state (Nolan, column 3, lines 28-44).

22. Column 3, lines 20-44 of Nolan and column 4, lines 16-50 of Nolan referenced by the Examiner merely disclose adjusting the alarm threshold based on activity and make no suggestion of determining whether measured heart motion is inconsistent with the determined level of physiological activity.

23. Column 3, lines 28-59 and column 9, lines 1-54 of Nolan, referenced by the Examiner disclose transmitting the alert signal whenever the alarm condition is met.

## IX. ARGUMENT (41.37(o))

### A. Claims 9-13, 15, 17, and 30 Are Not Anticipated by Nolan

Claim 9 calls for one or more electrocardiography electrodes (claim 9, lines 17-18). Nolan does not disclose cardiography electrodes. Rather than using electrodes (Nolan, column 2, lines 44-50), Nolan uses a coil 6 which generates an electromagnetic field which is altered by movement of nearby tissue (Nolan, column 9, lines 63 – column 11, line 19). Specifically, Nolan discloses an antenna system 12 including an antenna coil 6 (Nolan, column 9, line 63 – column 10, line 5). The coil 6 generates an electromagnetic field which impinges on organs that move or change in size, which motion or dimensional variability causes the input impedance of the coil 6 to change (Nolan, column 10, lines 47-56). An impedance measurement circuit 14 measures the impedance of current flow between the antenna and the body (Nolan, column 9, line 63 – column 10, line 17). More specifically, the impedance measurement circuit applies a voltage to the coil 6 (Nolan, column 11, line 62 – column 12, line 11). In particular, when the impedance measurement circuit generates measuring currents at the appropriate frequencies, the impedance which it measures reflects movements relating to respiration and to cardiac motion (Nolan, column 12, line 51 – column 13, line 4). The respiration and cardiac signals can be separated by frequency

filtering (Nolan, column 7, line 51 – column 13, line 4; column 15, lines 35-54). In conclusion, Nolan is directed to an implantable sensor which senses heart rate with actual contact with the heart. If external cardiac electrodes were added to Nolan, which Nolan teaches against at column 2, lines 44-50 and column 3, lines 24-26, and for which Nolan provides no enabling disclosure, one would render Nolan unable to function in its normal and intended manner. Thus, Nolan determines the pulse rate without using electrocardiography electrodes.

Second, claim 9 calls for determining whether activity sensor signals are above or below a predetermined threshold (claim 9, lines 25-28). By contrast, Nolan uses the activity signal to adjust the heart rate threshold with exercise (Nolan, column 20, lines 14-24; column 22, lines 24-67). Column 3, lines 60-66 and Column 5, lines 54-60 of Nolan referenced by the Examiner address the physiological actibity processing, but not the sensed activity signals. In the preferred embodiment of the present application, the activity threshold detector determines whether the patient is asleep or at rest versus whether the patient is active so that the patient will not be disturbed with non-urgent alarms when sleeping or resting. Rather than using such a predetermined threshold, Nolan increments the cardiac threshold up and down with a level of exercise.

Third, claim 9 calls for adaptively controlling the communication of information (claim 9, lines 31-37). In Nolan, the cardiac threshold may be adjusted with exercise or activity level as discussed above. However, when the cardiac level threshold is exceeded or other alarm events occur, this information is communicated (Nolan, column 23, lines 44-68; column 24, lines 31-52). Column 5, lines 50-62 and column 8, lines 48-50 of Nolan address adjusting the alarm criteria. But, lines 25-28 of claim 9 address adaptively controlling the **communication** of information, not the adjusting of alarm criteria. There is no adaptive control of the communications set forth in Nolan.

On page 2 of the Advisory Action of November 5, 2008, the Examiner indicated that the means for adaptively controlling the communication of information would require further search and/or further consideration (Advisory Action of November 5, 2008, page 2). This suggests (but does not concede) that the Examiner may concur that this limitation of claim 9 is not shown by Nolan.

Finally, claim 9 calls for adaptively controlling the communication of biological signal information to the patient through a user interface based on (1) the level of detected activity level to the predetermined threshold of the access detector, (2) the electrocardiography signals relative to the preset threshold of the arrhythmia detector, and/or (3) the detected system errors relative to the

predetermined criteria of the system error detector (claim 9, lines 31-37). Nolan does not disclose controlling communication of information based on any of these criteria. Again, as indicated above, Nolan adjusts a cardiac rate criteria based on physical activity and transmits an alarm signal in response to the criteria being met. The sending of the alarm signal is not conditional or adaptively controlled. Nolan adjusts the **alarm criteria**; whereas, claim 9 adaptively controls the **communication** of information.

Accordingly, it is submitted that claim 9 and claims 10-13, 15, 17, and 30 are not anticipated by and distinguish patentably and unobviously over the references of record.

B. **Claim 10 is Not Anticipated By Nolan**

Claim 10 calls for determining which of acoustical, tactical, or visual modes will communicate information based on whether the signals meet predetermined thresholds. Although Nolan has different alarm communication modes, Nolan does not determine which one of these modes to use based on the sensor signals meeting predetermined thresholds (Nolan, column 9, lines 10-22). Column 3, lines 60-66, column 8, lines 48-50, and column 9, lines 10-22 of Nolan relate to adjusting alarm criteria and not selecting among available modes of communication.

Accordingly, it is submitted that claim 10 is not anticipated by Nolan.

### C. Claim 15 is Patentable over Nolan in view of Toda

Claim 15 calls for the physical activity sensor to include a piezoelectric element. As discussed above, Nolan senses movement based on a change of inductance. Although Toda discloses that piezoelectric materials are known, the piezoelectric device of Toda is effective for the excitation of acoustic energy (Toda, [0001]). There is no disclosure or suggestion in Toda or Nolan as to how one would convert the piezoelectric ultrasonic transmission/excitation device of Toda into a sensing device for sensing physical activity. Even if one were to incorporate the Toda piezoelectric transducer into the Nolan device, it is unclear what function it would serve. Clearly, it would serve to radiate acoustic energy, but neither Toda nor Nolan provide any motivation to irradiate acoustic energy with an implanted patient monitor. Moreover, even if one were to incorporate the Toda piezoelectric device into the Nolan monitor, there is no disclosure or suggestion as to how the Nolan piezoelectric element could function as a physical activity sensor.

Accordingly, it is submitted that claim 15 distinguishes patentably and unobviously over Nolan and Toda.

D. **Claim 30 is Not Anticipated by Nolan**

Claim 30 calls for determining whether information is urgent or non-urgent. By contrast, Nolan only determines whether an alarm condition has or has not been met (Nolan, column 9, lines 40-54). Nolan does not go the extra step of determining if an alarm condition is urgent or non-urgent. Moreover, claim 30 calls for the processor to adaptively communicate and inhibit the communication of information in accordance with whether the patient is at rest or active, and with whether the information is urgent or non-urgent. As discussed above, Nolan does not communicate adaptively. Rather than adaptively controlling communications, Nolan is concerned with adjusting the alarm criteria. Moreover, Nolan does not communicate or inhibit the communication of information based on whether the patient is at rest or active, or whether the information is urgent or non-urgent. Nolan, as discussed above, may adjust the heart rate criteria based on whether a patient is exercising or not, but does not inhibit the communication of alarms or other information in accordance with either whether the patient is at rest or active, or whether the information is urgent or non-urgent. Nolan communicates whenever the alarm condition is met (Nolan, column 25, lines 7-63).

Accordingly, it is submitted that claim 30 is not anticipated by Nolan.

### E. Claims 23 and 31-33 Are Not Anticipated by Nolan and Distinguish Patentably Over the References of Record

For the reasons set forth in the 37 CFR 1.144 Petition, claims 23 and 31-33 stand or fall with corresponding apparatus claim 34.

### F. Claim 25 is Not Anticipated by Nolan

Claim 25 calls for the system monitor to classify detected malfunctions as either critical or non-critical, and to base which of at least two types of alarms are produced based on the classification of the detected malfunction as critical or non-critical. Although Nolan can have different types of alarms, the selection of the type of alarm is determined by and under the direction of the downloaded program code (Nolan, column 9, lines 10-22). Nolan does not select among types of alarms based on whether information is determined to be critical or non-critical. Indeed, Nolan does not differentiate between critical and non-critical alarm conditions. Moreover, Nolan issues the alarm signal based on an arrhythmia event, not on system malfunctions nor with the type of alarm being based on whether the malfunction is classified as critical or non-critical (Nolan, column 25, lines 47-63).

Accordingly, it is submitted that claim 25 is not anticipated by Nolan.

### G. Claims 27-29 Are Not Anticipated by Nolan

Claim 27 calls for adaptively controlling the communication of information in accordance with a level of the sensed physical activity. As discussed above, Nolan adjusts the cardiac rate threshold in accordance with whether the patient is exercising or not. Thus, Nolan uses detected physical activity to adjust a cardiac rate threshold; whereas, claim 27 calls for using the detected physical activity to control the communication of information. Nolan adjusts the cardiac rate threshold in accordance with exercise and whether the patient's heart rate is normal or abnormal for the exercise or non-exercise state (Nolan, column 3, lines 28-44). However, determining whether a patient's heart rate is normal for a given exercise state is adjusting the cardiac rate threshold with physical activity, i.e., adjusting the alarm condition with physical activity. But, adjusting the cardiac rate threshold with physical activity is not a determination of whether a biological signal is urgent or not urgent. Rather, Nolan determines whether an alarm condition is met.

Accordingly, it is submitted that claim 27 and claims 28 and 29 dependent therefrom are not anticipated by Nolan.

H. **Claim 28 is Not Anticipated by Nolan**

Claim 28 calls for communicating non-urgent information to a patient who is active and inhibiting the communication of non-urgent information to a patient is at rest. As discussed above, Nolan does not classify information as critical or non-critical. Nolan nearly determines whether an adjustable alarm criterion is met. Nor does Nolan have any suggestion of transmitting information which is non-critical when the patient is active and not when the patient is at rest. As discussed above, Nolan communicates alarm signals to the patient regardless whether the patient is at rest or active. There is no treatment of non-urgent or any other type of information differently when the patient is at rest or active.

Accordingly, it is submitted that claim 28 is not anticipated by Nolan.

I. **Claim 29 is Not Anticipated by Nolan**

Claim 29 is concerned with reducing false alarms by determining when the detected biological information signal is inconsistent with a level of physical activity, and for adaptively controlling the information to inhibit the communication of the information about the biological signal when the biological signal is inconsistent with the level of physiological activity. As indicated above, Nolan adjusts the cardiac rate criteria with physical activity, but makes no suggestion of determining

whether or not a detected biological information signal is inconsistent with the level of physiological activity. Moreover, Nolan transmits alarm signals when the detected biological information meets the adjustable criteria. There is no suggestion of transmitting or inhibiting the transmission of a biological information based on whether it is consistent with a level of physiological activity. Column 3, lines 20-44 of Nolan and column 4, lines 16-50 of Nolan referenced by the Examiner merely disclose adjusting the alarm threshold based on activity and make no suggestion of determining whether measured heart motion is inconsistent with the determined level of physiological activity.

Accordingly, it is submitted that claim 29 is not anticipated by Nolan.

### J. Claim 34 is Not Anticipated by Nolan

Claim 34 calls for transmitting the alert signal if the patient is active and inhibiting transmission of the alert signal when the patient is at rest. Column 3, lines 28-59 and column 9, lines 1-54 of Nolan, referenced by the Examiner disclose transmitting the alert signal whenever the alarm condition is met. There is no suggestion of inhibiting the transmission of the alarm signal if the patient is at rest. Rather, these sections of Nolan merely suggest adjusting the alarm criteria based on physical activity. Specifically, Nolan suggests raising the cardiac rate

threshold if the patient is exercising and lowering it if the patient is at rest. By having a lower heart rate alarm threshold when the patient is at rest, a heart rate signal is more likely to meet the at rest threshold and an alarm is more likely to be issued. The sections of Nolan referenced by the Examiner do not disclose inhibiting the transmission of the alarm signal if the patient is not exercising. The apparatus of claim 34 has the advantage of not awakening a sleeping patient or disturbing a patient at rest. By contrast, Nolan is merely concerned with raising the cardiac rate threshold when a patient is more active.

Accordingly, it is submitted that claim 34 is not anticipated by Nolan.

### K. Conclusion

For the reasons set forth in the preceding sections, it is submitted that no claims are anticipated by Nolan and that all claims distinguish patentably over Nolan. An early reversal of all rejections of all claims is requested.

Respectfully submitted,

Thomas E. Kocovsky, Jr.
Registration No. 28,383

FAY SHARPE LLP
The Halle Building, 5th Floor
1228 Euclid Avenue
Cleveland, OH 44115-1843
Telephone: (216) 363-9000 (main)
Telephone: (216) 363-9122 (direct)
Facsimile: (216) 363-9001
E-Mail: tkocovsky@faysharpe.com

APPENDIX

## X. CLAIMS SECTION (41.37(p))

1-8. (Cancelled)

9. (Rejected) A physiological monitoring system which comprises:

at least one sensor for detecting a biological signal, representative of a physiological characteristic of a monitor-wearing patient and generating an electrical signal representative of the biological signal;

at least one sensor for detecting physical activity of the patient and generating an electrical signal, representative of physical activity;

processing means, coupled to said sensors for processing said electrical signals;

an activity threshold detector coupled to said processing means for receiving said electrical signals representative of physical activity;

a user interface for communicating information about the detected biological signal to the patient;

means for adaptively controlling the communication of the information about the detected biological signal in accordance with a level of the sensed physical activity as determined by said activity threshold detector;

wherein the at least one sensor comprises one or more electrocardiography electrodes that sense electrocardiography signals from the patient, whereby the electrocardiography and physical activity sensors generate electrical signals representative of each respective biological signal;

wherein the processing means includes an arrhythmia threshold detector coupled to the electrocardiography sensor for receiving said electrical signals representative of the electrocardiography signals and determining whether the signals are below or above a preset threshold;

wherein the activity threshold detector is coupled with the activity sensor for receiving said electrical signals representative of the activity level of the patient and determining whether the signals are below or above a predetermined threshold;

further including a system error detector for detecting system errors and determining if the detected error meets pre-determined criteria; and

the means for adaptively controlling the communication includes a processor for controlling communication of system and biological signal information to the patient through the user interface based on (1) the level of the detected activity level relative to the predetermined threshold of said activity threshold detector, (2) the electrocardiography signals relative to the pre-set threshold of said arrhythmia threshold

detector, and/or (3) the detected system errors relative to the predetermined criteria of the system error detector.

10. (Rejected) The system of claim 9, wherein the user interface comprises:

an alarm circuit comprising acoustic, tactile, or visual modes of communicating information to the patient, and which mode is determined by processor based on whether the signals from the respective detectors meet pre-determined thresholds.

11. (Rejected) The system of claim 9, wherein processor further comprises:

a calibration means for pre-setting the pre-set threshold of the arrhythmia threshold detector based on processing of electrocardiography signals from the patient to generate a baseline of electrocardiography information.

12. (Rejected) The system of claim 9, further including:

a memory component, the processor saving the electrocardiography signals into the memory component such that electrode signals below the pre-set threshold of the arrhythmia threshold

detector are overwritten and electrocardiography signals above the pre-set threshold are saved in the memory component.

13. (Rejected) The system of claim 9, wherein the physical activity sensor comprises:

a transducer that detects chemical, electrical or mechanical characteristics of a monitor-wearing patient, representative of physical activity.

14. (Cancelled)

15. (Rejected) The system of claim 9, wherein the physical activity sensor is a passive transducer including a piezeoelectric element.

16. (Cancelled)

17. (Rejected) The system of claim 9, further comprising:

means of wireless communication to an external system, for communication of information about the patient and system state to the patient or to others.

18-22. (Cancelled)

23. (Withdrawn – Under Petition) A method for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient comprising the steps of:

attaching a physiological monitoring system to a patient;

detecting a selected physiological parameter of the patient;

sensing physical activity of the patient;

comparing the detected physiological parameter with a first pre-determined criteria to determine a physiological state of the patient reflecting an alarm condition;

generating an alert signal if the physiological condition of the patient reflects an alarm condition;

transmitting the alert signal to the patient, if the sensed physical activity of the patient indicates the patient is active and inhibiting the transmission of the alert signal if the sensed physical activity of the patient indicates that the patient is at rest.

24. (Cancelled)

25. (Rejected) A physiological monitoring system including:

at least one sensor for detecting a biological signal of a patient;

at least one sensor for detecting physical activity of the patient;

a processor coupled to the sensors, the processor including:

a biological signal processor for comparing the detected biological signal with biological signal threshold data and generating a biological signal alarm condition if the threshold is met, and

an activity threshold detector for processing the electrical signals representative of physical activity to determine physical activity of the patient,

an adaptive communication controller which determines alarm states based on the biological signal alarm condition and the determined physical activity;

a user interface controlled by the processor adaptive communication controller to produce at least two different types of alarms based on the biological signal alarm condition and the physical activity of the patient;

a system monitor which detects system malfunctions and classifies the detected malfunctions as critical or non-critical; and

wherein the user interface further bases the alarm type on the classification of any detected system malfunctions.

26. (Cancelled)

27. (Rejected) A physiological monitoring system which comprises:

at least one sensor for detecting a biological signal, representative of a physiological characteristic of a monitor-wearing patient and generating an electrical signal representative of the biological signal;

at least one sensor for detecting physical activity of the patient and generating an electrical signal, representative of physical activity;

processing means, coupled to said sensors for processing said electrical signals;

an activity threshold detector coupled to said processing means for receiving said electrical signals representative of physical activity, wherein the activity threshold detector determines when the patient is at rest or active;

a user interface for communicating information about the detected biological signal to the patient;

means for adaptively controlling the communication of the information about the detected biological signal in accordance with a level of the sensed physical activity as determined by said activity threshold detector;

a means for determining when the information about the detected biological signal is urgent or non-urgent.

28. (Rejected) The system of claim 27 wherein the means for adaptively controlling the communication of the information further:

in response to the information being urgent, communicates the information to the patient;

in response to the information being non-urgent and the patient being at rest, inhibits the communication of the information to the patient;

in response to the information being non-urgent and the patient being active, communicates the information to the patient.

29. (Rejected) The system of claim 27 further including:

a means for determining when the detected biological information signal is inconsistent with the level of physiological activity; and

wherein the means for adaptively controlling the information inhibits the communication of the information about the detailed biological signal when the means for determining when the detected biological information signal is inconsistent with the level of physiological activity determines that biological information signal is inconsistent with the level of physiological activity.

30. (Rejected) The system of claim 9 wherein the activity threshold detector determines when the patient is at least at rest and

active, and wherein the processor determines when the information is at least urgent and non-urgent; and

wherein the processor adaptively communicates and inhibits the communication of the information in accordance with whether the patient is at rest or active and whether the information is urgent or non-urgent.

31. (Withdrawn – Under Petition) The method of claim 23 further including:

in response to the sensed physical activity of the patient indicating that the patient is unconscious, transmitting the alert signal to a third party responder to supply emergency help.

32. (Withdrawn – Under Petition) The method of claim 23 further including:

comparing the detected physiological parameter with a second predetermined criteria indicative of a life-threatening physiological state;

in response to determining that the detected physiological parameter is indicative of a life-threatening physiological state, transmitting the alert signal to the patient regardless of the sensed physiological activity of the patient.

33. (Withdrawn – Under Petition) The method of claim 32 further including:

in response to determining from the sensed physical activity that the patient is engaged in normal waking activity inconsistent with the life-threatening physiological state, inhibiting the transmission of the alert signal to the patient.

34. (Rejected) An apparatus for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient comprising:

a physiological monitoring system for attachment to a patient;

means for detecting a selected physiological parameter of the patient with the physiological monitoring system;

means for sensing physical activity of the patient;

means for comparing the detected physiological parameter with a first pre-determined criteria to determine a physiological state of the patient reflecting an alarm condition;

means for generating an alert signal if the physiological condition of the patient reflects an alarm condition;

means for transmitting the alert signal to the patient if the sensed physical activity of the patient indicates the patient is active and

inhibiting the transmission of the alert signal if the sensed physical activity of the patient indicates that the patient is at rest.

APPENDIX (Continued)

## XI. CLAIM SUPPORT AND DRAWING ANALYSIS SECTION (41.37(r))

9. A physiological monitoring system **{10}** which comprises:

at least one sensor **{110, 112}** for detecting a biological signal, representative of a physiological characteristic of a monitor-wearing patient and generating an electrical signal representative of the biological signal; **{ p. 7, l. 24 – p. 8, l. 19; Figs. 1-3}**

at least one sensor **{110, 114}** for detecting physical activity of the patient and generating an electrical signal, representative of physical activity; **{p. 8, l. 19 – p. 9, l. 21; Fig. 1-3}**

processing means **{140, 142}**, coupled to said sensors **{112, 114}** for processing said electrical signals; **{ p. 9, l. 22 – p. 10, l. 21; Figs. 1-3}**

an activity threshold detector **{148}** coupled to said processing means **{142}** for receiving said electrical signals representative of physical activity; **{p. 4, l. 20-24; p. 13, l. 25 – p. 14, l. 24; Figs. 3, 4}**

a user interface **{170}** for communicating information about the detected biological signal to the patient; **{p. 12, l. 18 – p. 13, l. 28; Fig. 3}**

means **{109}** for adaptively controlling the communication of the information about the detected biological signal in accordance with a level of the sensed physical activity as determined by said activity

threshold detector {148}; {p. 4, l. 12-24; p. 6, l. 27 – p. 7, l. 11; p. 15, l. 27 – p. 17, l. 29; Figs. 1, 3, 4}

wherein the at least one sensor {110, 112} comprises one or more electrocardiography electrodes {112} that sense electrocardiography signals from the patient, whereby the electrocardiography and physical activity sensors {110} generate electrical signals representative of each respective biological signal; {p. 3, l. 18 – p. 4, l. 2; p. 8, l. 10 – p. 9, l. 21; Figs. 1, 3}

wherein the processing means includes an arrhythmia threshold detector {142} coupled to the electrocardiography sensor {112} for receiving said electrical signals representative of the electrocardiography signals and determining whether the signals are below or above a preset threshold; {p. 12, l. 1-17; Fig. 3}

wherein the activity threshold detector{148} is coupled with the activity sensor {114} for receiving said electrical signals representative of the activity level of the patient and determining whether the signals are below or above a predetermined threshold; {p. 4, l. 20-24; p. 13, l. 25 – p. 14, l. 24; Figs. 3, 4)

further including a system error detector {142, 290, 300} for detecting system errors and determining if the detected error meets pre-determined criteria {p. 14, l. 25 – p. 15, l. 11; p. 17, l. 12-18; Figs. 3, 4}; and

the means **{109}** for adaptively controlling the communication includes a processor **{142}** for controlling communication of system and biological signal information to the patient through the user interface **{170}** based on (1) the level of the detected activity level relative to the predetermined threshold of said activity threshold detector **{148}**, (2) the electrocardiography signals relative to the pre-set threshold of said arrhythmia threshold detector **{142}**, and/or (3) the detected system errors relative to the predetermined criteria of the system error detector **{142}**. **{p. 4, l. 12-19; p. 5, l. 15-19; p. 6, l. 27 – p. 7, l. 11; p. 14, l. 25 – p. 17, l. 29; Figs. 3, 4}**

10. The system of claim 9, wherein the user interface comprises:

an alarm circuit **{160}** comprising acoustic, tactile, or visual modes of communicating information to the patient, and which mode is determined by processor **{142}** based on whether the signals from the respective detectors **{146, 148}** meet pre-determined thresholds. **{p. 9, l. 27 – p. 10, l. 11; p. 12, l. 8 – p. 13, l. 18; p. 16, l. 26 – p. 17, l. 17; Figs. 3, 4}**

11. The system of claim 9, wherein processor **{142}** further comprises:

a calibration means **{142, 200}** for pre-setting the pre-set threshold of the arrhythmia threshold detector based on processing of electrocardiography signals from the patient to generate a baseline of electrocardiography information. **{p. 14, l. 14-26; Figs. 3, 4}**

12. The system of claim 9, further including:

a memory component **{144}**, the processor **{142}** saving the electrocardiography signals into the memory component such that electrode signals below the pre-set threshold of the arrhythmia threshold detector are overwritten and electrocardiography signals above the pre-set threshold are saved in the memory component. **{[/ 11. ;/ 16 – p. 12, l. 17; p. 15, l. 18-26; Figs. 3, 4}**

13. The system of claim 9, wherein the physical activity sensor **{114}** comprises:

a transducer that detects chemical, electrical or mechanical characteristics of a monitor-wearing patient, representative of physical activity. **{p. 4, l. 25-28; p. 9, l. 12-21; Fig. 3}**

15. The system of claim 9, wherein the physical activity sensor **{114}** is a passive transducer including a piezeoelectric element. **{p. 8, l. 22-27; Fig. 1, 3}**

17. The system of claim 9, further comprising:

means **{109}** of wireless communication to an external system, for communication of information about the patient and system state to the patient or to others. **{p. 9, l. 27 – p. 10, l. 11; p. 12, l. 1-17; p. 13, l. 3-18; p. 16, l. 26 – p. 17, l. 29; Figs. 1, 3, 4}**

23. A method for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient comprising the steps of:

attaching a physiological monitoring system **{10{** to a patient; **{p. 9, l. 22-26}**

detecting **{220}** a selected physiological parameter of the patient; **{p. 15, l. 18-26; Fig. 4}**

sensing **{220}** physical activity of the patient; **{p. 15, l. 18-26; Fig. 4}**

comparing **{230}** the detected physiological parameter with a first pre-determined criteria to determine a physiological state of the patient reflecting an alarm condition; **{p. 15, l. 27 – p. 16, l. 11; p. 16, l. 20-25; Fig. 4}**

generating **{260}** an alert signal if the physiological condition of the patient reflects an alarm condition; **{p. 16, l. 26 – p. 17, l. 11; Fig. 4}**

transmitting **{330}** the alert signal to the patient, if the sensed physical activity of the patient indicates the patient is active and inhibiting the transmission of the alert signal if the sensed physical activity of the patient indicates that the patient is at rest. **{p. 4, l. 12-24; p. 6, l. 27 – p. 7, l. 11; p. 17, l. 19-29; Fig. 4}**

25. A physiological monitoring system **{10}** including:

at least one sensor **{110, 112}** for detecting a biological signal of a patient; **{p. 7, l. 24 – p. 8, l. 19; Figs. 1, 3}**

at least one sensor **{110, 114}** for detecting physical activity of the patient; **{p. 8, l. 19 – p. 9, l. 21; Figs. 1, 3}**

a processor **{142}** coupled to the sensors **{110}**, the processor including: **{p. 9, l. 22 – p. 10, l. 21; Figs. 1, 3}**

a biological signal processor **{142, 230}** for comparing the detected biological signal with biological signal threshold data and generating a biological signal alarm condition if the threshold is met, and **{p. 10, l. 12-21; p. 12, l. 1-17; p. 15, l. 18 – p. 17, l. 29; Figs. 3, 4}**

an activity threshold detector **{148, 230}** for processing the electrical signals representative of physical activity to determine physical activity of the patient, **{p. 8, l. 22-27; p. 9, l. 12-21; p. 15, l. 18 – p. 17, l. 29; Figs. 3, 4}**

an adaptive communication controller **{109}** which determines alarm states based on the biological signal alarm condition and the determined physical activity; **{p. 4, l. 12-24; p. 6, l. 17 – p. 7, l. 11; p. 15, l. 27 – p. 17, l. 29; Figs. 1, 3, 4}**

a user interface **{170}** controlled by the processor adaptive communication controller to produce at least two different types of alarms based on the biological signal alarm condition and the physical activity of the patient; **{p. 4, l. 20-24; p. 12, l. 18 – p. 13, l. 18; Figs. 3, 4}**

a system monitor **{142, 290, 300}** which detects system malfunctions and classifies the detected malfunctions as critical or non-critical; and **{p. 14, l. 25 – p. 15, l. 11; p. 17, l. 12-18; Figs. 3, 4}**

wherein the user interface **{170}** further bases the alarm type on the classification of any detected system malfunctions. **{p. 5, l. 20-25; p. 6, l. 17 – p. 7, l. 11; p. 15, l. 27 – p. 17, l. 29; Figs. 1, 3, 4}**

27. A physiological monitoring system **{10}** which comprises:

at least one sensor **{110, 112}** for detecting a biological signal, representative of a physiological characteristic of a monitor-wearing patient and generating an electrical signal representative of the biological signal; **{p. 7, l. 24 – p. 8, l. 19; Figs. 1, 3}**

at least one sensor **{110, 114}** for detecting physical activity of the patient and generating an electrical signal, representative of physical activity; **{p. 8, l. 19 – p. 9, l. 21; Figs. 1, 3}**

processing means **{142}**, coupled to said sensors **{110}** for processing said electrical signals; **{p. 9, l. 22 – p. 10, l. 21; Figs. 1, 3}**

an activity threshold detector **{148}** coupled to said processing means **{142}** for receiving said electrical signals representative of physical activity, wherein the activity threshold detector determines when the patient is at rest or active; **{p. 4, l. 20-24; p. 13, l. 25 – p. 14, l. 24; Figs. 1, 3}**

a user interface **{170}** for communicating information about the detected biological signal to the patient; **{p. 12, l. 18 – p. 13, l. 18; Fig. 3}**

means **{109}** for adaptively controlling the communication of the information about the detected biological signal in accordance with a level of the sensed physical activity as determined by said activity threshold detector; **{p. 4, l. 12-24; p. 6, l. 27 – p. 7, l. 11; p. 15, l. 27 – p. 17, l. 29; Figs. 1, 3, 4}**

a means **{142, 230, 240}** for determining when the information about the detected biological signal is urgent or non-urgent. **{p. 4, l. 12-24; p. 5, l. 15-19; p. 6, l. 27 – p. 7, l. 11; p. 15, l. 27 – p. 17, l. 29; Figs. 1, 3, 4}**

28. The system of claim 27 wherein the means **{109}** for adaptively controlling the communication of the information further:

in response to the information being urgent, communicates the information to the patient **{260}**; **{p. 4, l. 12; p. 12, l. 1-17; p. 16, l. 20 – p. 17, l. 29; Figs. 3, 4}**

in response to the information being non-urgent and the patient being at rest, inhibits the communication of the information to the patient; **{p. 4, l. 12-24; p. 5, l. 15-19; p. 6, l. 27 – p. 7, l. 11; p. 15, l. 27 – p. 17, l. 29; Figs. 3, 4}**

in response to the information being non-urgent and the patient being active, communicates the information to the patient. **{p. 4, l. 12-24; p. 15, l. 27 – p. 16, l. 11; Figs. 3, 4}**

29. The system of claim 27 further including:

a means **{142, 230}** for determining when the detected biological information signal is inconsistent with the level of physiological activity **{p. 15, l. 27 – p. 16, l. 11; Fig. 4}**; and

wherein the means **{109}** for adaptively controlling the information inhibits the communication of the information about the detailed biological signal when the means for determining when the detected biological information signal is inconsistent with the level of physiological activity determines that biological information signal is

inconsistent with the level of physiological activity. **{p. 6, l. 27 – p. 7, l. 11; Fig. 3}**

30. The system of claim 9 wherein the activity threshold detector **{148}**determines when the patient is at least at rest and active **{p. 4, l. 12-24; p. 6, l. 27 – p. 7, l. 11; p. 15, l. 27 – p. 16, l. 19; p. 17, l. 19-29; Figs. 3, 4}**, and wherein the processor **{142, 300}** determines when the information is at least urgent and non-urgent **{p. 4, l. 12-19; p. 14, l. 25 – p. 15, l. 11; p. 15, l. 27 – p. 16, l. 12; p. 17, l. 12-18' Figs. 3, 4}**; and

wherein the processor **{142}** adaptively communicates and inhibits the communication of the information in accordance with whether the patient is at rest or active and whether the information is urgent or non-urgent. **{p. 4, l. 20-24; p. 5, l. 15-19; p. 15, l. 27 – p. 17, l. 27; Figs. 3, 4}**

31. The method of claim 23 further including:

in response to the sensed physical activity of the patient indicating that the patient is unconscious, transmitting the alert signal to a third party responder to supply emergency help. **{p. 12, l. 1-17; p. 16, l. 12-19]**

32. The method of claim 23 further including:

comparing the detected physiological parameter with a second predetermined criteria indicative of a life-threatening physiological state; **{p. 12, l. 1-17; p. 13, l. 3-24; p. 14, l. 14-24; p. 15, l. 27 – p. 16, l. 25}**

in response to determining that the detected physiological parameter is indicative of a life-threatening physiological state, transmitting the alert signal to the patient regardless of the sensed physiological activity of the patient. **{p. 12, l. 1-17; p. 16, l. 12-19}**

33. The method of claim 32 further including:

in response to determining from the sensed physical activity that the patient is engaged in normal waking activity inconsistent with the life-threatening physiological state, inhibiting the transmission of the alert signal to the patient. **{p. 5, l. 20-25; p. 6, l. 27 – p. 7, l. 11}**

34. An apparatus for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient **{p. 6, l. 27 – p. 7, l. 11; p. 24, l. 11-12; Figs. 1, 2}** comprising:

a physiological monitoring system **{10}** for attachment to a patient; **{p. 7, l. 19-23; p. 8, l. 10-21; p. 9, l. 22-26; p. 24, l. 13; Figs. 1, 2, 3}**

means **{110, 112}** for detecting a selected physiological parameter of the patient with the physiological monitoring system; **{p. 8, l. 10-21; p. 15, l. 18-26; p. 24, l. 14; Figs. 1, 3}**

means **{110, 114}** for sensing physical activity of the patient; **{p. 8, l. 19 – p. 9, l. 21; p. 15, l. 18-26; p. 24, l. 15; Figs. 1, 3}**

means **{142}** for comparing the detected physiological parameter with a first pre-determined criteria to determine a physiological state of the patient reflecting an alarm condition; **{p. 10, l. 12-21; p. 11, l. 1-4; p. 12, l. 1-16; p. 15, l. 27 – p. 16, l. 11; p. 16, l. 20-25; p. 24, l. 16-18; Fig. 3}**

means **{142, 230, 240}** for generating an alert signal if the physiological condition of the patient reflects an alarm condition; **{p. 12, l. 1-17; p. 13, l. 19-24; p. 16, l. 26 – p. 17, l. 11; p. 24, l. 19,20; Fig. 3}**

means **{109}** for transmitting the alert signal to the patient if the sensed physical activity of the patient indicates the patient is active and inhibiting the transmission of the alert signal if the sensed physical activity of the patient indicates that the patient is at rest. **{p. 4, l. 12-24; p. 6, l. 27 – p. 7, l. 11; p. 17, l. 19-29; p. 24, l. 21-22; Fig. 3}**

APPENDIX (Continued)

## XII. MEANS OR STEP PLUS FUNCTION ANALYSIS SECTION (41.37(s))

9. A physiological monitoring system **{10}** which comprises:

at least one sensor **{110, 112}** for detecting a biological signal, representative of a physiological characteristic of a monitor-wearing patient and generating an electrical signal representative of the biological signal; **{ p. 7, l. 24 – p. 8, l. 19; Figs. 1-3}**

at least one sensor **{110, 114}** for detecting physical activity of the patient and generating an electrical signal, representative of physical activity; **{p. 8, l. 19 – p. 9, l. 21; Fig. 1-3}**

processing means **{140, 142}**, coupled to said sensors **{112, 114}** for processing said electrical signals; **{ p. 9, l. 22 – p. 10, l. 21; Figs. 1-3}**

an activity threshold detector **{148}** coupled to said processing means **{142}** for receiving said electrical signals representative of physical activity; **{p. 4, l. 20-24; p. 13, l. 25 – p. 14, l. 24; Figs. 3, 4}**

a user interface **{170}** for communicating information about the detected biological signal to the patient; **{p. 12, l. 18 – p. 13, l. 28; Fig. 3}**

means **{109}** for adaptively controlling the communication of the information about the detected biological signal in accordance with a

level of the sensed physical activity as determined by said activity threshold detector **{148}**; **{p. 4, l. 12-24; p. 6, l. 27 – p. 7, l. 11; p. 15, l. 27 – p. 17, l. 29; Figs. 1, 3, 4}**

wherein the at least one sensor **{110, 112}** comprises one or more electrocardiography electrodes **{112}** that sense electrocardiography signals from the patient, whereby the electrocardiography and physical activity sensors **{110}** generate electrical signals representative of each respective biological signal; **{p. 3, l. 18 – p. 4, l. 2; p. 8, l. 10 – p. 9, l. 21; Figs. 1, 3}**

wherein the processing means includes an arrhythmia threshold detector **{142}** coupled to the electrocardiography sensor **{112}** for receiving said electrical signals representative of the electrocardiography signals and determining whether the signals are below or above a preset threshold; **{p. 12, l. 1-17; Fig. 3}**

wherein the activity threshold detector**{148}** is coupled with the activity sensor **{114}** for receiving said electrical signals representative of the activity level of the patient and determining whether the signals are below or above a predetermined threshold; **{p. 4, l. 20-24; p. 13, l. 25 – p. 14, l. 24; Figs. 3, 4)**

further including a system error detector **{142, 290, 300}** for detecting system errors and determining if the detected error meets pre-

determined criteria **{p. 14, l. 25 – p. 15, l. 11; p. 17, l. 12-18; Figs. 3, 4}**; and

the means **{109}** for adaptively controlling the communication includes a processor **{142}** for controlling communication of system and biological signal information to the patient through the user interface **{170}** based on (1) the level of the detected activity level relative to the predetermined threshold of said activity threshold detector **{148}**, (2) the electrocardiography signals relative to the pre-set threshold of said arrhythmia threshold detector **{142}**, and/or (3) the detected system errors relative to the predetermined criteria of the system error detector **{142}**. **{p. 4, l. 12-19; p. 5, l. 15-19; p. 6, l. 27 – p. 7, l. 11; p. 14, l. 25 – p. 17, l. 29; Figs. 3, 4}**

10. The system of claim 9, wherein the user interface comprises:

an alarm circuit **{160}** comprising acoustic, tactile, or visual modes of communicating information to the patient, and which mode is determined by processor **{142}** based on whether the signals from the respective detectors **{146, 148}** meet pre-determined thresholds. **{p. 9, l. 27 – p. 10, l. 11; p. 12, l. 8 – p. 13, l. 18; p. 16, l. 26 – p. 17, l. 17; Figs. 3, 4}**

11. The system of claim 9, wherein processor **{142}** further comprises:

a calibration means **{142, 200}** for pre-setting the pre-set threshold of the arrhythmia threshold detector based on processing of electrocardiography signals from the patient to generate a baseline of electrocardiography information. **{p. 14, l. 14-26; Figs. 3, 4}**

12. The system of claim 9, further including:

a memory component **{144}**, the processor **{142}** saving the electrocardiography signals into the memory component such that electrode signals below the pre-set threshold of the arrhythmia threshold detector are overwritten and electrocardiography signals above the pre-set threshold are saved in the memory component. **{[/ 11. ;/ 16 – p. 12, l. 17; p. 15, l. 18-26; Figs. 3, 4}**

13. The system of claim 9, wherein the physical activity sensor **{114}** comprises:

a transducer that detects chemical, electrical or mechanical characteristics of a monitor-wearing patient, representative of physical activity. **{p. 4, l. 25-28; p. 9, l. 12-21; Fig. 3}**

15. The system of claim 9, wherein the physical activity sensor **{114}** is a passive transducer including a piezeoelectric element. **{p. 8, l. 22-27; Fig. 1, 3}**

17. The system of claim 9, further comprising:

means **{109}** of wireless communication to an external system, for communication of information about the patient and system state to the patient or to others. **{p. 9, l. 27 – p. 10, l. 11; p. 12, l. 1-17; p. 13, l. 3-18; p. 16, l. 26 – p. 17, l. 29; Figs. 1, 3, 4}**

23. A method for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient comprising the steps of:

attaching a physiological monitoring system **{10{** to a patient; **{p. 9, l. 22-26}**

detecting **{220}** a selected physiological parameter of the patient; **{p. 15, l. 18-26; Fig. 4}**

sensing **{220}** physical activity of the patient; **{p. 15, l. 18-26; Fig. 4}**

comparing **{230}** the detected physiological parameter with a first pre-determined criteria to determine a physiological state of the patient

reflecting an alarm condition; {**p. 15, l. 27 – p. 16, l. 11; p. 16, l. 20-25; Fig. 4**}

generating {**260**} an alert signal if the physiological condition of the patient reflects an alarm condition; {**p. 16, l. 26 – p. 17, l. 11; Fig. 4**}

transmitting {**330**} the alert signal to the patient, if the sensed physical activity of the patient indicates the patient is active and inhibiting the transmission of the alert signal if the sensed physical activity of the patient indicates that the patient is at rest. {**p. 4, l. 12-24; p. 6, l. 27 – p. 7, l. 11; p. 17, l. 19-29; Fig. 4**}

25. A physiological monitoring system {**10**} including:

at least one sensor {**110, 112**} for detecting a biological signal of a patient; {**p. 7, l. 24 – p. 8, l. 19; Figs. 1, 3**}

at least one sensor {**110, 114**} for detecting physical activity of the patient; {**p. 8, l. 19 – p. 9, l. 21; Figs. 1, 3**}

a processor {**142**} coupled to the sensors {**110**}, the processor including: {**p. 9, l. 22 – p. 10, l. 21; Figs. 1, 3**}

a biological signal processor {**142, 230**} for comparing the detected biological signal with biological signal threshold data and generating a biological signal alarm condition if the threshold is met, and {**p. 10, l. 12-21; p. 12, l. 1-17; p. 15, l. 18 – p. 17, l. 29; Figs. 3, 4**}

an activity threshold detector **{148, 230}** for processing the electrical signals representative of physical activity to determine physical activity of the patient, **{p. 8, l. 22-27; p. 9, l. 12-21; p. 15, l. 18 – p. 17, l. 29; Figs. 3, 4}**

an adaptive communication controller **{109}** which determines alarm states based on the biological signal alarm condition and the determined physical activity; **{p. 4, l. 12-24; p. 6, l. 17 – p. 7, l. 11; p. 15, l. 27 – p. 17, l. 29; Figs. 1, 3, 4}**

a user interface **{170}** controlled by the processor adaptive communication controller to produce at least two different types of alarms based on the biological signal alarm condition and the physical activity of the patient; **{p. 4, l. 20-24; p. 12, l. 18 – p. 13, l. 18; Figs. 3, 4}**

a system monitor **{142, 290, 300}** which detects system malfunctions and classifies the detected malfunctions as critical or non-critical; and **{p. 14, l. 25 – p. 15, l. 11; p. 17, l. 12-18; Figs. 3, 4}**

wherein the user interface **{170}** further bases the alarm type on the classification of any detected system malfunctions. **{p. 5, l. 20-25; p. 6, l. 17 – p. 7, l. 11; p. 15, l. 27 – p. 17, l. 29; Figs. 1, 3, 4}**

27. A physiological monitoring system **{10}** which comprises:

at least one sensor **{110, 112}** for detecting a biological signal, representative of a physiological characteristic of a monitor-wearing

patient and generating an electrical signal representative of the biological signal; **{p. 7, l. 24 – p. 8, l. 19; Figs. 1, 3}**

at least one sensor **{110, 114}** for detecting physical activity of the patient and generating an electrical signal, representative of physical activity; **{p. 8, l. 19 – p. 9, l. 21; Figs. 1, 3}**

processing means **{142}**, coupled to said sensors **{110}** for processing said electrical signals; **{p. 9, l. 22 – p. 10, l. 21; Figs. 1, 3}**

an activity threshold detector **{148}** coupled to said processing means **{142}** for receiving said electrical signals representative of physical activity, wherein the activity threshold detector determines when the patient is at rest or active; **{p. 4, l. 20-24; p. 13, l. 25 – p. 14, l. 24; Figs. 1, 3}**

a user interface **{170}** for communicating information about the detected biological signal to the patient; **{p. 12, l. 18 – p. 13, l. 18; Fig. 3}**

means **{109}** for adaptively controlling the communication of the information about the detected biological signal in accordance with a level of the sensed physical activity as determined by said activity threshold detector; **{p. 4, l. 12-24; p. 6, l. 27 – p. 7, l. 11; p. 15, l. 27 – p. 17, l. 29; Figs. 1, 3, 4}**

a means **{142, 230, 240}** for determining when the information about the detected biological signal is urgent or non-urgent. **{p. 4,**

**l. 12-24; p. 5, l. 15-19; p. 6, l. 27 – p. 7, l. 11; p. 15, l. 27 – p. 17, l. 29; Figs. 1, 3, 4}**

28. The system of claim 27 wherein the means **{109}** for adaptively controlling the communication of the information further:

in response to the information being urgent, communicates the information to the patient **{260}**; **{p. 4, l. 12; p. 12, l. 1-17; p. 16, l. 20 – p. 17, l. 29; Figs. 3, 4}**

in response to the information being non-urgent and the patient being at rest, inhibits the communication of the information to the patient; **{p. 4, l. 12-24; p. 5, l. 15-19; p. 6, l. 27 – p. 7, l. 11; p. 15, l. 27 – p. 17, l. 29; Figs. 3, 4}**

in response to the information being non-urgent and the patient being active, communicates the information to the patient. **{p. 4, l. 12-24; p. 15, l. 27 – p. 16, l. 11; Figs. 3, 4}**

29. The system of claim 27 further including:

a means **{142, 230}** for determining when the detected biological information signal is inconsistent with the level of physiological activity **{p. 15, l. 27 – p. 16, l. 11; Fig. 4}**; and

wherein the means **{109}** for adaptively controlling the information inhibits the communication of the information about the

detailed biological signal when the means for determining when the detected biological information signal is inconsistent with the level of physiological activity determines that biological information signal is inconsistent with the level of physiological activity. **{p. 6, l. 27 – p. 7, l. 11; Fig. 3}**

30. The system of claim 9 wherein the activity threshold detector **{148}**determines when the patient is at least at rest and active **{p. 4, l. 12-24; p. 6, l. 27 – p. 7, l. 11; p. 15, l. 27 – p. 16, l. 19; p. 17, l. 19-29; Figs. 3, 4}**, and wherein the processor **{142, 300}** determines when the information is at least urgent and non-urgent **{p. 4, l. 12-19; p. 14, l. 25 – p. 15, l. 11; p. 15, l. 27 – p. 16, l. 12; p. 17, l. 12-18' Figs. 3, 4}**; and

wherein the processor **{142}** adaptively communicates and inhibits the communication of the information in accordance with whether the patient is at rest or active and whether the information is urgent or non-urgent. **{p. 4, l. 20-24; p. 5, l. 15-19; p. 15, l. 27 – p. 17, l. 27; Figs. 3, 4}**

31. The method of claim 23 further including:

in response to the sensed physical activity of the patient indicating that the patient is unconscious, transmitting the alert signal to a third party responder to supply emergency help. **{p. 12, l. 1-17; p. 16, l. 12-19]**

32. The method of claim 23 further including:

comparing the detected physiological parameter with a second predetermined criteria indicative of a life-threatening physiological state; **{p. 12, l. 1-17; p. 13, l. 3-24; p. 14, l. 14-24; p. 15, l. 27 – p. 16, l. 25}**

in response to determining that the detected physiological parameter is indicative of a life-threatening physiological state, transmitting the alert signal to the patient regardless of the sensed physiological activity of the patient. **{p. 12, l. 1-17; p. 16, l. 12-19}**

33. The method of claim 32 further including:

in response to determining from the sensed physical activity that the patient is engaged in normal waking activity inconsistent with the life-threatening physiological state, inhibiting the transmission of the alert signal to the patient. **{p. 5, l. 20-25; p. 6, l. 27 – p. 7, l. 11}**

34. An apparatus for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient **{p. 6, l. 27 – p. 7, l. 11; p. 24, l. 11-12; Figs. 1, 2}** comprising:

a physiological monitoring system **{10}** for attachment to a patient; **{p. 7, l. 19-23; p. 8, l. 10-21; p. 9, l. 22-26; p. 24, l. 13; Figs. 1, 2, 3}**

means **{110, 112}** for detecting a selected physiological parameter of the patient with the physiological monitoring system; **{p. 8, l. 10-21; p. 15, l. 18-26; p. 24, l. 14; Figs. 1, 3}**

means **{110, 114}** for sensing physical activity of the patient; **{p. 8, l. 19 – p. 9, l. 21; p. 15, l. 18-26; p. 24, l. 15; Figs. 1, 3}**

means **{142}** for comparing the detected physiological parameter with a first pre-determined criteria to determine a physiological state of the patient reflecting an alarm condition; **{p. 10, l. 12-21; p. 11, l. 1-4; p. 12, l. 1-16; p. 15, l. 27 – p. 16, l. 11; p. 16, l. 20-25; p. 24, l. 16-18; Fig. 3}**

means **{142, 230, 240}** for generating an alert signal if the physiological condition of the patient reflects an alarm condition; **{p. 12, l. 1-17; p. 13, l. 19-24; p. 16, l. 26 – p. 17, l. 11; p. 24, l. 19,20; Fig. 3}**

means **{109}** for transmitting the alert signal to the patient if the sensed physical activity of the patient indicates the patient is active and inhibiting the transmission of the alert signal if the sensed physical activity of the patient indicates that the patient is at rest. **{p. 4, l. 12-24; p. 6, l. 27 – p. 7, l. 11; p. 17, l. 19-29; p. 24, l. 21-22; Fig. 3}**

APPENDIX (Continued)

## XIII. EVIDENCE SECTION (41.37(t))

Not applicable

APPENDIX (Continued)

## XIV. RELATED CASES SECTION (41.37(u))

None